

## **REMARKS**

Claims 13, 14, 16, and 17 are pending and under examination. Applicants acknowledge with appreciation the Office's withdrawal of the prior rejections under 35 U.S.C. §§ 112, first paragraph, and 103. Office Action, page 2. The Office now rejects the pending claims under 35 U.S.C. § 102(b) as allegedly anticipated. Before addressing this rejection, Applicants request clarification on the status of Applicants' claim to priority.

### **Priority Documents**

In the prior Office Action, the Office indicated that Applicants did not file certified copies of priority documents JP 2004-021808 and JP 2003-282691 with the Office or English translations of these priority documents. As Applicants explained, the Form PCT/IB/304 indicated that the priority documents were submitted to the international bureau. For the Office's convenience, however, Applicants attached to the response filed on August 25, 2008, certified copies of JP 2004-021808 and JP 2003-282691 and their English translations as available on the European Patent Office's web site. To date, the Office has not acknowledged Applicants' claim to priority under 35 U.S.C. § 119. See Office Action, page 1.

Applicants earnestly request that the Office acknowledge its claim to priority based on JP 2004-021808 and JP 2003-282691 in the next Office Action.

### **Anticipation**

The Office currently rejects claims 13, 14, 16, and 17 under 35 U.S.C. § 102(b) as allegedly anticipated by Urashima et al. (WO 97/13515; "Urashima"). See Office Action, page 2. According to the Office, Urashima "teaches the treatment of Sjogren's syndrome and 'dry eye' syndrome with administration of the elected compound." *Id.*

Acknowledging that Urashima does not teach the effectiveness of the “elected compound to accelerate salivation,” the Office nonetheless contends that the “claimed compound is expected to necessarily have the claimed effect on acceleration of salivation. . . .” *Id.* The Office reasons that “the very teaching of the identical compound elected necessarily means that the claimed acceleration of salivation is necessarily present. . . .” *Id.* at 3. Applicants respectfully disagree.

The Office bases its rejection on Urashima’s alleged teaching of the compound recited in the rejected claims. Applicants note, however, that claims 13, 14, 16, and 17 are method claims, not composition claims. Independent claim 16 recites a “method for accelerating salivation” while independent claim 17 recites a “method for treatment of xerostomia.” As the Office noted, Urashima teaches nothing about the ability of the recited carbostyryl compound to accelerate salivation and therefore does not teach a “method for accelerating salivation” or a “method for treatment of xerostomia.”

Applicants also note that the claimed methods recite oral administration of the carbostyryl compound. The recited carbostyryl compound is a very weak agonist for the muscarine M3 receptor, which reduces negative side-effects that can result from M3 receptor stimulation. See specification, page 13, lines 9-21. For example, cevimeline hydrochloride, is used as a salivation accelerator, but this compound also acts as a muscarine receptor agonist, leading to digestive system side effects such as nausea, vomiting, anorexia, abdominal discomfort, and stomachache. See *Id.* at page 3, line 23 to page 4, line 6. In contrast, the carbostyryl compound recited in method claims 16 and 17 was known as an anti-ulcer agent, an agent for treating gastric inflammation, and an agent for protecting against intestinal mucosa disorder without the above-listed negative side effects on the digestive system. See *Id.* at page 4, lines 12-22. Thus, the claimed

method relates to a new use of the recited carbostyryl compound in such a way as to minimize the negative impacts that other salivation accelerators have on the digestive system. Urashima does not teach anything about these added benefits, let alone even a "method for accelerating salivation" or a "method for treatment of xerostomia."

Applicants therefore request that the Office withdraw this rejection.

Conclusions

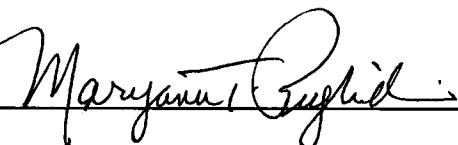
In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of claims 13, 14, 16, and 17.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: May 7, 2009

By: 

Maryann T. Puglielli  
Reg. No. 52,138  
(202) 408-6054